

AMENDMENTS TO SPECIFICATION:

Please delete the paragraph starting on page 12, line 25, of the specification in its entirety and replace it with the following replacement paragraph:

FIGS. 1-4 are a front perspective view, right side view, bottom view, and back view, respectively, of the system inclusive of field-portable analyzer 10 and disposable blood sampling device 12 in accordance with the present invention. With combined reference to FIGS. 1-4, the present analyzer 10 accepts the disposable blood sampling device 12 (containing a small blood sample) in a sample door 20. Door 20 is closed, and an automatic test sequence is carried out by which the analyzer 10 accurately measures the hematocrit (HCT) and/or hemoglobin (HGB) from the blood sample, which remains safely contained within the disposable 12. Analyzer 10 is a point of care HCT and/or HGB measurement device of hand-held size, and generally includes a portable housing 30 having a battery pack (obscured) seated in a downwardly protruding rear stand 32. The sample door 20 is side-oriented door pivoted to the housing and formed with a contoured ~~pocket~~ sample chamber 22 for convenient guided-insertion of disposable 12. The sample door 20 latches shut to precisely align and lock the disposable 20 in place in a sample chamber (to be described). A set of sealed pressure-sensitive control keys 50 allows user-control of the testing process. In the illustrated embodiment three keys 50 are provided, one for device ON/OFF, one for test initiation, and one for calibration and diagnostics. All three keys 50 are coupled to an internal circuit board (as will be described) that seats a processor and memory (thus keys 50 may be alternately programmed as desired). A, LCD display screen 40 displays the device status and the measured HCT and/or HGB concentration of the blood sample to the user. The housing 30 encloses the battery pack as well as the circuit board on which a processor and a plurality of supporting electronic components reside for initiating the test sequence. The test

sequence includes generating ultrasonic pulses into the blood sample (still in disposable sampling device 12), measuring time of flight of said ultrasonic pulses through the blood sample, as well as temperature of the blood sample, calculating HCT and/or HGB from the speed of sound and temperature measurements, and displaying the HCT or HGB measurement on the display screen 40.

Please delete the paragraph starting on page 18, line 16, of the specification in its entirety and replace it with the following replacement paragraph:

The enlarged illustration to the right of FIG. 9 illustrates the connection between the opposing end of tube 11 and testing region 20 of the disposable device 12. The testing region 20 is an open window formed by a transverse aperture 21 through the front and back of the supporting frame of the sampling device 12. Preferably, the aperture 21 is cylindrical to define a round-walled testing channel 25 with cylindrical cross-section. Square or rectangular cross sections are also suitable, but a cylindrical shape (round aperture with flat sides) deters air bubbles from forming in the testing channel 25, while also minimizing the amount of blood required for accurate testing. Two rims surround the aperture 21 on both the front and back surface and these are slightly raised to form sealing rings ~~22~~ 26 (see FIG. 8) against the walls of the analyzer 10. The sealing rings ~~22~~ 26 form the contact points with the sampling device 12 when it is inserted into the analyzer 10 and the door 20 is latched shut to lock the sampling device 12 in place. Disposable device 12 is squeezed tightly between two walls of the sampling chamber inside the analyzer 10, said walls mating with the sealing rings ~~22~~ 26 to hermetically seal off the testing channel 25. The volume of the sealed testing channel 25 may range from 0.01 to 1 ml.

Please delete the paragraph starting on page 20, line 8, of the specification in its entirety and replace it with the following replacement paragraph

While the preferred embodiment of the disposable device 12 is made generally of hard rubber with integral rubber sealing rings ~~22~~ 26, one skilled in the art will understand that the device 12 may be formed substantially of hard plastic with separate rubber grommet-type sealing rings ~~22~~ 26. Other possible materials include glass, polystyrene, polyamide, polyvinylchloride, polycarbonate, silicone, polypropylene, polyurethane, latex or polyethylene. The choice of materials and surface finishes for the device 12 are preferably chosen to prolong the onset of coagulation (i.e. Pebax is suitable). This is particularly desirable when using untreated capillary blood in an ultrasonic analyzer because it has been demonstrated that the biochemical process of coagulation changes the speed of sound over time. Surface finishes are preferably smooth to minimize the surface area, allowing the blood to flow more freely through the device and prolong the onset of coagulation.

Please delete the paragraph starting on page 20, line 19, of the specification in its entirety and replace it with the following replacement paragraph:

The sampling device 12 may be manufactured by one-shot molding, or two-shot molding in separate halves that are then hot-welded together, the sealing rings ~~22~~ 26 and other flexible components being integrally molded or added separately. The various parts may be connected by snaps, adhesive, ultrasonic welding, or any other method of securing differing plastic or rubber materials. The sampling device 12 may also be formed using blow molding.

Please delete the paragraph starting on page 22, line 7, of the specification in its entirety and replace it with the following replacement paragraph:

The frame structure of the disposable device 12 is specifically designed to mate with ~~port~~ sample chamber 22 of the analyzer 10 (See FIGS. 1 and 2), and the ~~port~~ sample chamber 22 requires certain structure to work with the device 12. The ~~port~~ sample chamber 22 structure includes the door 20 hinged to the main housing 30 of the analyzer 10 and closing and latching shut to capture and seat the sampling device 12 inside with one or more sensors 227 directed orthogonally through (and sealing off) the test cell 25 of the disposable 12 as shown in FIG. 9. Thus, the disposable device 12 is inserted into ~~port~~ sample chamber 22 with blood sample already in the capillary tube 11.

Please delete the paragraph starting on page 22, line 14, of the specification in its entirety and replace it with the following replacement paragraph:

While the embodiment of FIGS. 6-9 relies on a micro-pump engaged to the disposable 12 orifice, FIG. 10 is a composite drawing showing an alternative disposable embodiment 300 in which the action of the micro-pump in analyzer 10 is replaced by an on-board actuator bulb 332 on the disposable 300. The actuator bulb 332 is preferably made of flexible rubber or plastic and may be integrally molded in the sampling device 300 (by molding and welding two half-sections or by unitary molding of the device 300). The actuator bulb 332 is sealed and feeds a pressure differential through a connected actuator tube 331 into testing chamber 325. The actuator bulb 332 protrudes above the plane of the device 300, and the ~~port~~ sample chamber 22 is formed with constricted sides (or protrusions) at a predetermined depth. Thus, as device 300 is inserted, the sides of the ~~port~~ sample chamber 22 depress the actuator bulb 332 forcing air through actuator

tube 331 into testing ~~cylinder~~ chamber 325 and out apertures 321, and then releases the bulb 332 as the bulb travels past. This way, when the device 300 is inserted into ~~port~~ sample chamber 22 with blood sample already in the capillary tube 11, the walls of the sample chamber 22 squeeze and release the bulb 332. As before, sealing rings ~~322~~ 26 around the ~~test~~ testing chamber 325 act as a wiping mechanism against the sensor housing surfaces 328 (which contain one or more sensors 327) within the analyzer 300. Rather than constricted walls, the analyzer 10 may comprise a mechanism 310 for depressing and releasing the actuator bulb ~~32~~ 332 as shown (this may be a conventional solenoid). Either way, this creates a vacuum which draws the blood stored in the capillary tube 311 into the testing chamber ~~326~~ 325. Once the analysis is complete, the sampling device 300 is withdrawn, the sides of the ~~port~~ sample chamber 22 are again positioned to depress the actuator bulb ~~331~~ 332, thus using air pressure to force the blood out of the testing chamber ~~326~~ 325 and back into capillary tube 311. As the device 300 is removed from the analyzer 10, the sealing rings ~~322~~ 26 again serve as a wiping mechanism, cleaning off the sensing surfaces 328. The danger of inadvertent exposure to the blood is eliminated by the sequential use of capillary action and pressure-differential to move the blood from containment, to sample chamber, and back, automatically upon insertion and withdrawal.

Please delete the paragraph starting on page 24, line 15, of the specification in its entirety and replace it with the following replacement paragraph:

FIG. 11 is a side cross-section illustrating the fit of the disposable sampling device 12 in the ~~sampling~~ sample chamber 22 of analyzer 10, and FIG. 12 is an operational schematic. The ~~port~~ sample chamber 22 contains one or more transducers 227 having raised sensing surfaces 228 that engage the sealing rings ~~22~~ 26 of device 12, the sealing rings ~~22~~ 26 acting as a wiping

mechanism, cleaning the parallel sensing surfaces 228 of the sensors 227 within the analyzer 10. When fully inserted, the disposable 12 bottoms out in door 20 guaranteeing that the disposable 12 is located correctly with respect to the sensing surfaces 228. The sealing rings ~~22~~ 26 then form a hermetic seal against the sensing surfaces 228, thereby forming a closed test cell 25. ~~FIG. 8(D)~~ FIG. 11 illustrates the final position of the disposable 12 with micropump 210 facing the actuator region 30 and raised sensing surfaces 228 around sensor 227 engaged with the sealing rings ~~22~~ 26 so that the sensor 227 communicates with the testing channel 25. Micro-pump 210 may be any of a variety of commercially-available micro-pumps such sold by Micropump, Inc., such as their leak-free sealless magnetic drive low flow pumps for metering and dosing liquids.

Please delete the paragraph starting on page 25, line 5, of the specification in its entirety and replace it with the following replacement paragraph:

Again, latching the door 20 activates a microswitch (not shown) that in turn initiates a pumping sequence at micro-pump 210 to draw the blood in capillary tube 11 into the test cell 25. As seen at ~~FIG. 8(D)~~ FIG. 11, the micro-pump 210 engages actuator orifice 32 and sucks the blood sample out of capillary tube 11 into testing cell 25.

Please delete the paragraph starting on page 27, line 16, of the specification in its entirety and replace it with the following replacement paragraph:

Once the analysis is complete, micro-pump 210 exerts a small amount of reverse pressure to force the blood out of the testing cell 25 and back into capillary tube 11. As the device 12 is removed from the analyzer 10, the sealing rings ~~22~~ 26 again serve as a wiping mechanism, cleaning off the sensing surfaces 228. The danger of inadvertent exposure to the blood is

eliminated by the sequential use of capillary action and pressure-differential to move the blood from containment, to sample chamber, and back, automatically upon insertion and withdrawal.

Please delete the paragraph starting on page 28, line 15, of the specification in its entirety and replace it with the following replacement paragraph:

FIG. 14 is a top perspective view of the analyzer 10 with top housing section 30A removed to illustrate operation of the door 20 latching mechanism 400 during insertion of the sampling device 12 into sample chamber 22. The door 20 is shown open in FIG. 14. FIG. 15 is a similar view with door 20 closed and the primary components of the latching mechanism 400 exploded. With combined reference to FIGS. 14-15, the sample door 20 is side-oriented door with opposing hinges 422 that snap-into pivot joints in the lower housing 30B. The door 20 is formed with a contoured ~~pocket~~ sample chamber 22 to guide slidable insertion of disposable 12. The sample door 20 then latches shut to precisely align and lock the disposable 20 in place in the sample chamber 22.